

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS				REVIEW DATE 4/28/00		NAME OF FOREIGN LABORATORY Central Meat Control Laboratory									
FOREIGN COUNTRY LABORATORY REVIEW															
FOREIGN GOV'T AGENCY Dept. of Agriculture, Food, and Rural Development			CITY & COUNTRY Dublin 15, Ireland			ADDRESS OF LABORATORY Abbotstown, Castleknock									
NAME OF REVIEWER Dr. Gary D. Bolstad			NAME OF FOREIGN OFFICIAL Drs. Cecil Alexander, Paul Rafter, and Canice Bennett												
Residue Code/Name			200	203	400	501	800	907	923						
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A					
	Sampling Frequency	02		A	A	A	A	A	A	A					
	Timely Analyses	03		C	C	C	C	C	C	C					
	Compositing Procedure	04		O	O	O	O	O	O	O					
	Interpret Comp Data	05		O	O	O	O	O	O	O					
	Data Reporting	06		A	A	A	A	A	A	A					
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	GC	A					
	Correct Tissue(s)	08		A	C	A	C	C	Liv	Liv					
	Equipment Operation	09		mi-cro	A	A	A	mi-cro	A	A					
	Instrument Printouts	10		N/A	A	A	A	N/A	A	A					
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	+/-	A	A	A	+/-	A	A					
	Recovery Frequency	12		A	A	A	A	A	A	A					
	Percent Recovery	13		qual	A	A	A	qual	50-70	40					
	Check Sample Frequency	14		C	C	C	C	N/A	C	C					
	All analyst w/Check Samples	15		A	A	A	A	N/A	A	A					
	Corrective Actions	16		C	C	C	C	C	C	C					
	International Check Samples	17		A	O	A	O	O	O	O					
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	A	O	O	O					
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

Dr. Gary D. Bolstad

DATE

4/28/00

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 4/28/00	NAME OF FOREIGN LABORATORY Central Meat Control Laboratory
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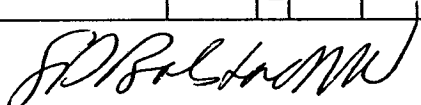
ANALYST	DATE	DETERMINATION	RESULTS	DATE	DETERMINATION	RESULTS
B.McA.	4/17	Clenbuterol	124.3%	4/10	Clenbuterol	93%
D.McE.	4/13	Chloramphenicol	84.13%	4/10	Clenbuterol	86.4%
M.H.	4/25	Zeranol	83.7%	4/10	Zeranol	80.2%
J.K.	1/30	Tetracycline	72.1%	1/28	Doxycycline	53.2%
A.R.	1/13	Ivermectin	45%	1/7	Ivermectin	45%
B.C.	2/23	Lead	104.4%	2/22	Cadmium	97%
M.F.	4/26	Inhibitory Substances	neg	4/25	Inhibitory Substances	neg
J.M.	1/10	Sulfonamides	neg	8/10/99	Sulfonamides	neg
B.G.	4/13	Thyreostatics	neg	4/17	Thyreostatics	neg
D.G.	2/23	Carbadox	48%	2/27	Carbadox	50.03%

- 03 Most turnaround times (the amount of time between sample reception in the laboratory until analysis is complete) did not meet the FSIS expectation of ten working days. The turnaround times for routine field samples in this laboratory were: for routine antibiotics 6 weeks, for chloramphenicol up to 5 weeks, for tetracyclines up to 9 months, for diethylstilbestrol (DES) 3-4 months, for sulfonamides up to 4 months, for carbadox 2 months, and for ivermectin 6 months. Note: analyses for antibiotics from suspect animals were completed within 24 hours of reception.
- 11 No minimum detection level had been determined for ivermectin or carbadox. The "decision level" was set at 30 ppb: if the amount detected was less than 30 ppb, it was considered negative; if greater than 30 ppb, it was considered positive.
- 14 The intra-laboratory check sample (CS) program did not meet FSIS standards, which require that each analyst must participate in a CS program, at least once per calendar month, for each class of substances for which he/she performs the field analyses for the national residue testing program. There had not been a quality manager in this laboratory for more than a year, since the previous one had accepted a new job offer and had not been replaced. Check samples for antibiotics were being done every 3 months. No check samples for chloramphenicol had been done for some two years (the person in charge of this section stated that there was "not enough time." The last CS for tetracyclines was done in October 1999, and for DES—9/24/99 (due to failure of a spectrophotometer—a new one was ordered), for sulfas August 1998 (the section supervisor stated that no extra CS program was necessary for sulfas, since each kit came with its own controls). Check samples for carbadox, ivermectin, and sedatives were being run together with field samples, which were being held for up to 3-6 months so that several could be run at the same time.
- 15 There was no written program for corrective actions in the event that an analyst's proficiency did not meet expectations. As stated above, there had not been a quality manager in this laboratory for more than a year.

No formal standards books were maintained in the section for chloramphenicol and DES. The supervisor stated that he "[goes] by experience." Expiration dates of analytes were not tracked. No record was being kept of the dates of preparation for the standard solutions.

The standards book for carbadox and ivermectin did not contain the source of the analytes, lot numbers, or expiration dates.

NOTE: This laboratory was owned and operated by the Department of Agriculture, Food, and Rural Development (DAFRD), but it had not been accredited. DAFRD officials had submitted a "draft work plan" with a request for additional resources to establish qualification for accreditation. Attempts by the DAFRD staff involved with the laboratory to improve the situation had been made, and the auditor was informed that the process must be approved by the Chief Veterinary Officer, the Irish Personnel division, the Secretary General, and the Department of Finance. The same official stated that an independent study of the laboratory's operations had determined that an additional twenty staff were needed.

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RESIDUE	ITEM	COMMENTS																												
		<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">ANALYST</th> <th style="width: 10%;">DATE</th> <th style="width: 20%;">DETERMINATION</th> <th style="width: 15%;">RESULTS</th> <th style="width: 10%;">DATE</th> <th style="width: 20%;">DETERMINATION</th> <th style="width: 10%;">RESULTS</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">3/10</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">104%</td> <td style="text-align: center;">3/10</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">94%</td> </tr> <tr> <td style="text-align: center;">2</td> <td style="text-align: center;">3/15</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">102%</td> <td style="text-align: center;">3/10</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">88%</td> </tr> <tr> <td style="text-align: center;">3</td> <td style="text-align: center;">3/2</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">88%</td> <td style="text-align: center;">3/2</td> <td style="text-align: center;">Aldrin</td> <td style="text-align: center;">101%</td> </tr> </tbody> </table> <p>Note: the three analysts were functioning as a team: one analyst did not necessarily run a complete determination from beginning to end on his/her own.</p>	ANALYST	DATE	DETERMINATION	RESULTS	DATE	DETERMINATION	RESULTS	1	3/10	Aldrin	104%	3/10	Aldrin	94%	2	3/15	Aldrin	102%	3/10	Aldrin	88%	3	3/2	Aldrin	88%	3/2	Aldrin	101%
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All	03	Turnaround times (the amount of time from reception in the laboratory until the analyses are complete) for all compounds was approximately two months. FSIS expects turnaround times of ten working days.																												
All	14	Check samples were being run together with each batch of field samples (approximately every two months). FSIS standards require that each analyst must participate in a check sample program, at least once per calendar month, for each class of substances for which he/she performs the field analyses for the national residue testing program.																												

Microbiology Laboratory Audit

General

Name & location of lab: *Independent Micro Lab, Ltd. Portlaoise, Ireland, 4/27/00*

Private or gov't lab? *Private*

How & when was accreditation obtained? *Accredited with the Irish Nat'l Accreditation Board since 1993.*

How & how often is accreditation maintained? *Yearly audits (one takes a full day).*

Proficiency samples? *Provided by Public Health Laboratory Service in London*

When and how is payment for analysis provided? *Paid by the establishments, billed on a monthly basis.*

Are results released before payment is received? *Yes—immediately upon completion of the analysis.*

Methodology

What methods are used for *Salmonella* and/or *E. coli*? *ISO 6579, 1993, equivalent to AOAC and BAM (FDA's Bacteriological Analytical Manual).*

What buffer (and what volume) is used for:

1. *Salmonella* sponge samples? *20 ml of a solution mixed by dissolving 9.5 grams of Maximum Recovery Diluent (MRD) in 1 liter of water. MRD is produced by Oxoid Ltd, Basingstoke, Hampshire, England, and the solution then contains 1 gram/liter peptone and 8.5 g/l sodium chloride.*
2. *E. coli* sponge samples? *20 ml of the same solution.*
3. *Salmonella* ground beef samples? *No US-approved establishments produce any ground beef.*
4. Poultry? *Ireland is not certified to export poultry to the U.S.*
5. What is the formulation of the Buffered Peptone Water you use? *Per liter: peptone 10.0g, NaCl 5.0 g, Disodium phosphate 3.5g, and monopotassium phosphate 1.5 g.*

What analytical controls are used? *Spiked samples are routinely run monthly to ensure the lower limits of recovery..*

Are they used concurrent with each sample set? *No – monthly.*

How are results calculated and expressed? *Salmonella*: presence of absence in the 25-gram piece of sponge used to swab the carcasses; *E. coli* = MPN/cm²

How are samples received & recorded? *By courier; each sample is given a unique identification number by the laboratory with a computerized Laboratory Information Laboratory System (LIMS). Condition of the sample and integrity of the sample container are noted and documented.*

Are HACCP samples analyzed on the day of receipt? *Yes*

How are results recorded:

1. Data sheets/work sheets? *There is a separate work sheet for each test. The results are also stored in the LIMS. Only 5 approved signatories within the laboratory have access to the program.*
2. Log books? *No*

How and to whom are results reported? *Reported by mail to the quality control manager in the establishment and, on a monthly basis, a summary is sent to DAFRD. DAFRD is not notified immediately by the laboratory in the event of positive results; the responsible establishment individual would do so.*

Proficiency issues

What are the qualifications of the analysts performing the individual tasks within a method? *All are graduates of the appropriate applied science courses.*

What are the qualifications of the direct supervisor of the analysts? *Master's degree in Agricultural Science and a B.Sc. degree in Food Science and Technology*

Proficiency samples:

1. For individual analysts or for the lab as a whole? *Individual analysts.*
2. What organisms are used? *Salmonella, Listeria, Staphylococcus aureus, Clostridia, E. coli, and others.*
3. How many are done, and how often? *12 times per year (monthly).*
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? *Yes*
5. How many colony-forming units (CFUs) per gram are in the proficiency samples provided to analysts? *Salmonella: between 1 and 100 CFUs per 25 grams.*